

ENVIRONMENTAL PROTECTION AGENCY

Status of NAFTA Harmonization of Environmental Fate Data Requirements and Test Protocols for Pesticide Registration; Notice of Availability

SUMMARY: The purpose of this notice is to provide an update on the progress being made in harmonizing environmental fate data requirements and test protocols under the NAFTA Technical Working Group on Pesticides. The U.S. Environmental Protection Agency and Canada's Pest Management Regulatory Agency (PMRA) have committed to harmonize pesticide regulatory tools so that work sharing and joint review activities become routine. This is important for achieving the goal of one North American market for pesticides.

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The following tables apply to conventional chemical pesticides proposed for use on terrestrial field crops and demonstrate the status of harmonization between the U.S. and Canada for pesticide registration data requirements and test protocols related to environmental fate. In general, there are many areas of agreement between the two countries, and only a few differences. Although the EPA and PMRA have reached technical agreement on all but one of the environmental fate data requirements and protocols for outdoor terrestrial food uses, these agreements have not yet been granted official status through each country's respective regulatory process, nor are they yet reflected in the official regulatory documents of each country. Some of the agreements reflected here indicate that changes to the U.S. 40 Code of Federal Regulations Part 158 (40 CFR 158) will be necessary. The EPA is in the process of developing a regulatory proposal for all Part 158 data requirements. Thus, the changes reflected in these tables will be incorporated into that regulatory development process.

Harmonized Environmental Fate Data Requirements

Fully Harmonized Data Requirements and Protocols for the Technical Grade Active Ingredient (TGAI)

Study Title	Harmonized Requirement	EPA Guideline Number	PMRA Data Code
Hydrolysis	R	161-1	8.2.3.2
Photodegradation in Water	R	161-2	8.2.3.3.2
Photodegradation in Air	CR	161-4	8.2.3.3.3
Aerobic Soil Metabolism	R	162-1	8.2.3.4.2

The following requirements have been agreed to at the working level, but are not reflected in the U.S. 40 CFR 158 or in a PMRA Regulatory Directive.

Agreement at the Working Level in the EPA and the PMRA on Aquatic Biotransformation (metabolism) Data Requirements and Protocols

Study Title	Harmonized Requirement	EPA Guideline Number	PMRA Data Code
<i>TGAI (Requirements and Protocols)</i>			
Anaerobic Soil Metabolism	R	162-2	8.2.3.4.4
Aerobic Aquatic Metabolism	R	162-4	8.2.3.5.2 8.2.3.5.4
Anaerobic Aquatic Metabolism	CR ¹	162-3	8.2.3.5.6
<i>End-use Product (EP) (Requirements)</i>			
Aquatic Field Dissipation	CR ²	164-2	8.3.3

¹ Likely to be upgraded from conditional (CR) to required (R) for the purposes of model input.

² The PMRA will accept U.S. field studies, if conducted at appropriate sites in relevant ecoregions.

The following requirements have been agreed to at the working level, but are not reflected in a PMRA Regulatory Directive.

Agreement at the Working Level in the EPA and the PMRA on Soil Mobility Data Requirements and Protocols for the TGAI

Study Title	Harmonized Requirement	EPA Guideline Number	PMRA Data Code
Adsorption/Desorption	R	163-1	8.2.4.2
Soil Column Leaching	R	163-1	8.2.4.3

Essentially Harmonized Environmental Fate Data Requirements

The PMRA will accept data required and accepted by the EPA.

For the TGAI

Study Title	EPA Requirement	PMRA Requirement	EPA Guideline Number	PMRA Data Code
Photodegradation on Soil	CR ³	R ³	161-3	8.2.3.3.1
Laboratory Volatility	CR ⁴	CR ⁴	163-2	8.2.4.5
Accumulation in Fish	CR ⁵	CR ⁵	165-4	9.5.6

³ Both EPA and the PMRA would require the study for surface applications and would waive the requirement for application solely by injection or incorporation.

⁴ The PMRA conditional requirement is with the TGAI if volatilization is indicated by vapor pressure or Henry's Law Constant, whereas the EPA conditional requirement is with the EP on a case-by-case basis, depending on use pattern and other pertinent factors, including vapor pressure and Henry's Law Constant. A waiver of a TGAI laboratory volatility, on the basis of the submission of an EP study, would be accepted by the PMRA.

⁵ Neither the EPA nor the PMRA would require this study if the value of the octanol/water partition coefficient (K_{ow}) is less than 1000 (i.e., $\log K_{ow} < 3$). Additionally, the EPA would normally not require this study if the active ingredient and/or its principal degradation product(s): 1) will not reach water, or 2) will not persist in water (i.e., half-life of approximately four days or less). NB: This data requirement appears in Part 9 (Environmental Toxicology) of the PMRA DACO Table.

Both countries require terrestrial field dissipation studies, although there is not yet agreement on the protocol or the number of sites.

For the EP

Study Title	EPA Requirement	PMRA Requirement	EPA Guideline Number	PMRA Data Code
Soil Field Dissipation	R	R ⁶	164-1	8.3.2

⁶ The PMRA will accept U.S. field studies, if conducted at appropriate sites in relevant ecoregions.

For the Parent Compound and Transformation Products

Study Title	EPA Requirement	PMRA Requirement	EPA Guideline Number	PMRA Data Code
Analytical Methodology for Soil	R	R	164-1	8.2.2.1
Analytical Methodology for Sediment	CR	R	164-2	8.2.2.2
Analytical Methodology for Water	R	R	166-1	8.2.2.3
Analytical Methodology for Biota	CR	R	164-1	8.2.2.4

In addition, it is recognized that each country can require special studies depending on the circumstances.